

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 5061-5080

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5061. Honey with Royal Jelly. (F. D. C. No. 39022. S. No. 33-991 M.)

QUANTITY: 17 1-lb., 8-oz. jars, at Tulsa, Okla., in possession of Akin Natural Food.

SHIPPED: 2-29-56, from Los Angeles, Calif., by Western Commerce Corp.

LABEL IN PART: (Jar) "Topaz Brand Cream Of The Tropics Honey With Royal Jelly Wonder Food Of The Queen Bee Each teaspoonful contains approx. 100 mg. of Royal Jelly."

ACCOMPANYING LABELING: (Leaflet) "Royal Jelly by R. B. Willson."

RESULTS OF INVESTIGATION: The above-mentioned leaflet was printed locally for the consignee.

LIBELED: 4-6-56; amended 5-22-56, N. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for nervous and glandular disorders, including aging, cerebral neuritis, arthritis, autointoxication from tobacco, asthma, failing eyesight, sterility in women, impotence in men, and deficient lactation in women; and 505 (a)—the article was a new drug which may not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6-12-56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS

5062. Elemin vitamin and mineral tablets. (F. D. C. No. 37266. S. No. 5-566 M.)

INFORMATION FILED: 8-3-55, E. Dist. Wis., against John P. Sheeran, Milwaukee, Wis.

ALLEGED VIOLATION: 11-16-54, the defendant, in the course of a sales talk to an individual, made oral representations holding out the article as an effective treatment for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale.